Remarks

Claims 1-30 are pending in the subject application. By this Amendment, applicants have amended claims 1, 13, and 22, and have canceled claims 2-7, 9-12, 14-21, and 23-29 without prejudice or disclaimer to applicants' right to pursue the subject matter of these claims in the future.

Applicants maintain that amended claims 1, 13, and 22 raise no issue of new matter and are fully supported by the specification as filed. Support for amended claim 1 may be found inter alia in the specification, as originally filed, on page 4, lines 5-12; page 16, lines 20-24; page 8, lines 9-10 and 24; and at page 6, lines 15 and 19. Support for amended claim 13 may be found inter alia in the specification, as originally filed, on page 4, lines 13-21; page 8, line 23 through page 9 line 30; page 15, line 16 through page 16, line 5; page 16, lines 20-24; and page 6, lines 15 and 19. Support for amended claim 22 may be found inter alia in the specification, as originally filed, on page 4, lines 13-21; page 8, line 23 through page 9 line 30; page 15, line 16 through page 16, line 5; page 16, lines 20-24; and page 6, lines 15-19. Accordingly, applicants respectfully request entry of this Amendment. Upon entry of this Amendment, claims 1, 8, 13, 22, and 30 will be pending and under examination.

Claims Rejected under 35 U.S.C. §112 (Enablement)

The Examiner stated that claims 1-12 remain rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement for gene therapy as detailed in the first Office Action on the merits, mailed 3 July, 2002. The Examiner stated that applicants argue "the claimed subject matter is not directed to establishing a gene therapy, but instead to regulating

expression of an exogenous gene introduced by an extant gene therapy", but that this is not persuasive because enablement for the method still requires enablement for gene therapy because the method is explicitly limited to being practiced in the context of gene therapy, and that gene therapy was not enabled at the time of filing.

In response, applicants respectfully traverse the Examiner's rejection. Applicants maintain that gene therapies existed and were known to those skilled in the art at the time of filing. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove amended the claims. As amended, the claims no longer recite the term "gene therapy" and are directed to methods for regulating the expression of an exogenous gene introduced into a cell. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

The Examiner stated that claims 1-12 were further rejected on the grounds that the specification allegedly fails to enable the full scope of the vectors comprising electromagnetic response elements used in the claimed method. The Examiner further stated that the disclosure, while being enabling for an expression vector comprising a chimeric regulatory sequence comprising the 900 bp region of the c-myc promoter from -353 to -1257, relative to the transcriptional start site, fused to the first 111 base pairs upstream of the transcription initiation site of the HSP70 promoter and a method of regulating the expression of a nucleic acid in a cell in vitro, does not reasonably provide enablement for any promoter comprising at least one exogenous electromagnetic response element or a method of using the enabled promoter in vivo.

With regard to the Examiner's rejection of claims 1-12 and 13-30 as allegedly not enabled in their full scope under 35 U.S.C. §112, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove amended the claims to recite a gene promoter comprising a 900 base pair segment of c-myc promoter containing nCTCTn electromagnetic field response elements fused to a HSP70 gene promoter heat shock responsive element. Applicants note that a working example of such a method employing the described promoter is described in the specification as filed. Accordingly, applicants maintain that the method as claimed is fully enabled by the specification as filed, and respectfully request that the Examiner reconsider and withdraw this ground of rejection

Claims Rejected under 35 U.S.C. §112 (Written Description)

The Examiner stated that claims 1-30 were further rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner also stated that applicants have amended the claims such that they now recite that the promoter EMREs comprise the sequence nCTCTn, which applicants state is readily identifiable. The Examiner stated that an adequate description of the claimed subject matter requires that the modified promoters be described themselves. The Examiner stated that other than a 900 base pair module from the c-myc promoter fused to the HSP70 heat shock promoter, the specification provides no description of the promoter used in the claimed method.

In response, applicants respectfully traverse the Examiner's

rejection. However, in order to expedite prosecution, but without conceding the correctness of the Examiner's position, applicants have hereinabove amended the claims to recite a gene promoter comprising a 900 base pair segment of c-myc promoter containing nCTCTn electromagnetic field response elements fused to a HSP70 gene promoter heat shock responsive element. Applicants note that such a construct is described in the specification as filed, as acknowledged by the Examiner.

Claims Rejected under 35 U.S.C. §112 (Written Description)

The Examiner stated that claims 4, 7, 17, 20, 26 and 29 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner stated that in the instant case, the claims have been amended to recite that the electromagnetic response elements lie within some range which is now defined as relative to the transcription initiation site of the c-myc or HSP70 gene promoter. The Examiner further stated that to support the new limitations, applicants cite the second and third paragraphs on page 6 of the specification. The Examiner stated that, however, the cited teachings state, "[t]he nCTCTn sequences may lie between about -230 and about -160 in the HSP70 gene promoter" and "[t]he nCTCTn sequences may lie between about -1257 and about -353 in the c-myc gene promoter." The Examiner also stated that the cited teachings do not explicitly state that the range is provided relative to the transcriptional start site and the skilled artisan would not assume that the limitation is inherent to the teaching because the +1 site within a gene is more frequently identified as the translational start site, rather than the transcriptional start site.

In response, applicants note that, in addition to the support

previously cited, support exists at page 7, lines 12 to 29, where the specification states, *inter alia*, "upstream from the transcription initiation site". Accordingly, applicants maintain that new matter was not added to the claims, and respectfully request that the Examiner reconsider and withdraw this ground of rejection. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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